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Filed : **June 11, 1999**

REMARKS

Claims 89, 105 and 123 have been amended by this paper, Claims 45-88, 100-104 and 132-155 are cancelled by this paper without prejudice to their subsequent inclusion in a later application, and Claims 90-99, 106-122, and 124-131 remain unchanged by this amendment. Hence, by this paper, Claims 89-99 and 105-131 are presented for further examination.

In an Office Action mailed May 20, 2003, the Examiner stated that the “amendment to the claims filed on April 23, 2003 does not comply with the requirements of 37 C.F.R. § 1.121(c) because Claim 131 which previously depended on Claim 123 now depends on Claim 126.” The Examiner advised that “Applicant has not provided the required changes to the claims in the form of brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system.”

In response, Applicant respectfully notes that the amendment to Claim 131 which changed dependency from Claim 123 to Claim 126 was presented in an Amendment mailed July 29, 2002. Applicant submits that the above-referenced amendment was correctly submitted in that paper, with the appropriate bracketing and underlining being included in a document entitled “Marked Up Copy of the Claims to Show Changes” which was appended to the Amendment. A copy of that Amendment is submitted herewith as “Exhibit A”. The dependency of Claim 131 has not been further amended by any papers filed in connection with the above-identified pending patent application, including the amendment mailed April 22, 2003.

In view of the above, Applicant submits that the amendment of Claim 131 presented in the paper filed July 29, 2002 properly complies with the requirements of 37 C.F.R. § 1.121(c). Accordingly, Applicant respectfully submits that no further action is needed to properly indicate the dependency of Claim 131 from Claim 126.

In the Office Action mailed May 20, 2003, the Examiner rejected Claims 89-99 and 105-131 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner stated that the “specification does not support the use of the assay plate structure being provided with encoded information associated with at least one of the upper and lower surfaces, the encoded information including address information for at least one of the reaction sites, with the embodiments not in the form of disc, ...” Although Applicant disagrees with the Examiner’s position regarding support in the specification, Applicant has amended independent Claims 89 and 123 to indicate that they define a “disc assay plate

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structure". Furthermore, independent Claim 123 has been amended to indicate that it is directed to "[a]n optically transparent disc structure". Applicant respectfully submits that the specification clearly provides support for claims directed to such disc structures, including, for example, the structure illustrated in Figure 3 and described on page 12, line 21 - page 13, line 25.

The Examiner also stated that "the specification does not support the recitation of the "encoded information containing address information for at least one of the reaction sites". Applicant respectfully submits that it would be clear to one skilled in the art that providing address information used to provide accurate location information on the part of the disc which is being scanned by the light beam inherently can include providing address information for at least one of the reaction sites, since knowledge of the location of the reaction sites is necessary to properly position equipment to scan the site with the light beam. For example, the assay described on page 15, line 6 through page 16, line 33 is described with reference to the embodiment shown in Figure 4b, using reaction sites comprising the wells 76. A discussion of the process for measuring the results of the reactions is presented at page 16, line 33 - page 17 line 15. There it is noted, for example, that "the reaction results in an optical change, from transparent to coloured (blue) and which is measured using an optical detector which measures light transmissivity through the disk and wells." (See, page 15, line 35- page 16, line 1). The process locates the plate 64 in a light transmissive microscope 80 and conducts an analysis by "measuring mean grey scale values in centre of wells quantified by NIH Image software." (Page 17, lines 10-11). Thus, it is apparent that in order to properly operate the optical measuring devices which scan the disc by a light beam and then detect that light in order to evaluate reactions in the wells, it is necessary to know the location of the well which is being scanned by the light beam. This information is provided by means of the encoded address information.

Nevertheless, in order to move prosecution forward, and to provide claim language which is clearly supported by the specification, and also covers the circumstance where address information is to be provided for wells which are being scanned, as discussed above, Applicant has amended independent Claims 89, 105 and 123 to include appropriate language which both has clear support and accomplishes this purpose.

In particular, each of Claims 89, 105 and 123 have been amended to define "encoded information stored in at least one of said upper and lower surfaces so as to be readable by a scanned light beam, said encoded information including address information providing location

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information as to the part of said disc being scanned by the light beam.” The Examiner has acknowledged that the specification teaches that the “address information can be used to provide accurate location information on the part of the disk which is being scanned by the light beam.” (Specification, page 13, lines 17-19).

In view of the above, Applicant respectfully submits that the Claims, as presented herein, comply with the written description requirement. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

In the Office Action mailed May 20, 2003, the Examiner rejected Claims 89-93, 96, 98-99, 105-120, 123-129 and 131 under 35 U.S.C. § 103(a) as being unpatentable over Croteau *et al.* (U.S. Patent No. 5,700,655) in view of Merkh *et al.* (U.S. Patent No. 5,281,540).

With respect to Croteau *et al.*, the Examiner states that, among other things, this reference does not teach the “disc structure including digitally encoded address information including address information for at least one of the reaction sites.” The Examiner states that Merkh *et al.* does teach, among other things, a disc structure 18 which is divided into sector inserts 80 comprising wells, “a sector insert having digitally encoded address information 94 for use with a device having an optical inspection means 316.” However, Applicant has not been able to identify where the reference teaches that the “code means 94” comprises address information “providing location information as to the part of said disc being scanned by the light beam.” (See, e.g. Claims 89, 105, and 123). Instead, Merkh *et al.* states that in

“a preferred embodiment, each code means includes, among other items of information, a code 318 identifying the lot from which the capture reagents bound to the test sites 84 of the cartridge originated. In addition, if multiple cartridges containing different pre-selected panels of assays and manufactured using capture reagents from the same lot are available, the code 318 also preferably includes a panel identifying code.” (Column 32, lines 16-23).

The Merkh *et al.* device does not provide address information on the cartridges, since such address could necessarily change based upon which one of the plurality of carousel openings 98 is selected for insertion of the particular cartridge 80. Accordingly, the Merkh *et al.* system uses a laborious process to define the locations of the various cartridges 80 on the carousel 18. This includes, a process wherein the operator:

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“preferably manually records a patient identification code on the reaction cartridge 80, loads the cartridge 80 into the opening in the carousel 18 and enters the patient identification code on the keypad. The microprocessor 315 responds to the entry of the patient identification code on the keypad 34 in accordance with the control program by storing the location of the cartridge on the carousel 18 with the patient identification code in RAM 334.” (Column 36, lines 30-39).

This process is repeated for each cartridge which is used on the carousel. This information is then accessed from the memory in order to appropriately position the optical reader 32 to perform the various process steps in creating and evaluating the reactions.

In contrast, the device defined in Applicant's claims comprises, among other things, encoded information stored in at least one of said upper and lower surfaces (as opposed to information stored on bar code structures, as is taught by Merkh *et al.*) so as to be readable by a scanned light beam, said encoded information including address information providing location information as to the part of said disc being scanned by the light beam. (See, e.g., Claims 89, 105 and 123). This encoded information is stored in a surface of the disc assay plate structure, and thus provides a direct reference to define the address of information being scanned. No separate reference to a memory, or storage of information by a user is necessary in order to accurately identify the relevant location on the disc which can include reaction sites. The ability to store the address information on a surface of the disc assay plate thus provides accurate position identification which is not susceptible to the error which may occur on user entered data, such as is required by Merkh *et al.* It also reduces the amount of data storage and processing that is required in the Merkh *et al.* system, where such address information must be stored in a separate memory.

In view of the above, Applicant respectfully submits that independent Claims 89, 105 and 123 define subject matter which is neither taught nor would have been made obvious by the Croteau *et al.* or Merkh *et al.* references, taken individually or in combination. Thus, Applicant submits that independent Claims 89, 105 and 123 define subject matter which is patentable over the art of record. Furthermore, since each of Claims 90-93, 96, 98-99, 106-120, 124-129 and 131 each depend from one of independent Claims 89, 105 or 123, these dependent claims also define subject matter which is patentable over the art of record for at least the reasons set forth above with respect to independent Claims 89, 105 and 123. Accordingly, Applicant respectfully

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submits that Claims 89-93, 96, 98-99, 105-120, 123-129 and 131 define subject matter which is patentable over the art of record.

In the Office Action mailed May 20, 2003, the Examiner also rejected Claims 97, 116 and 130 under 35 U.S.C. § 103(a) as being unpatentable over Croteau *et al.* in view of Merkh *et al.* as applied to Claim 96 above, and further in view of Takase *et al.* (EP 417 305 A1). In addition, the Examiner rejected Claims 121-122 under 35 U.S.C. § 103(a) as being unpatentable over Croteau *et al.* in view of Merkh *et al.* as applied to Claim 105 above, and further in view of Ford (U.S. Patent No. 4,722,598).

Applicant notes that Claims 97, 116, 121-122 and 130 each depend from one of Claims 89, 105 or 123. Accordingly, for the reasons set forth above, Applicant submits that these dependent claims each define subject matter which is patentable over the art of record for at least the reasons set forth above with respect to independent Claims 89, 105 and 123.

In view of the forgoing, Applicant respectfully submits that Claims 89-99 and 105-131, as presented herein, define subject matter that is patentable over the art of record. Accordingly, Applicant respectfully submits that Claims 89-99 and 105-131 are now in condition for immediate allowance and such prompt allowance of the same is respectfully requested.

CONCLUSION

The Applicant has endeavored to address all of the concerns of the Examiner in view of the recent Office Action directed to the above-identified application. Accordingly, amendments to the claims, the reasons therefor and arguments in support of the patentability of the pending claims are presented above.

The specific changes to the amended claims are shown in the above section entitled **IN THE CLAIMS**. On this set of pages, the insertions are underlined while the deletions are stricken through.

Any claim amendments which are not specifically discussed in the above remarks are made to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art..

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejection is specifically requested. If the Examiner finds any remaining impediment

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to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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